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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,524	05/10/2001	Su-Chen Chang	205032000420	6780

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/853,524	CHANG ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 10-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-2, 5-6, 8-11, and 14-18, with traverse, with regard to Group II, claims 3-6, 9, and 12-18, filed 10/15/02 in Paper No. 7 is acknowledged and has been entered. No traversal was made with respect to Group III. Applicant's amendment is also acknowledged and has been entered. Claims 7-9 have been cancelled. Claims 19 and 20 have been added.

Applicant's traversal is on the grounds that thromboembolic disorders benefit from inhibiting thrombosis and inhibiting platelet aggregation using the claimed composition. Therefore, as interrelated, no added burden is apparent

Applicant's argument is deemed persuasive. Therefore, claims 3-4 and 12-13 have been rejoined with Group I. Accordingly, claims 1-6 and 10-20 are being prosecuted on the merits. Currently, claims 1-6 and 10-20 are pending and are under examination.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings in this application are also objected to by the Draftsperson (see PTO-948 attached). Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "an effective amount of adenosine" because it is unclear, as recited, what is encompassed in using the term "effective" which is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 2 is vague and indefinite in reciting, "an effective amount of adenosine" because it is unclear, as recited, what is encompassed in using the term "effective" which is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 3 is vague and indefinite in reciting, "an effective amount of adenosine" because it is unclear, as recited, what is encompassed in using the term "effective" which is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claims 4-6 have improper antecedent basis problems in reciting, "A method according to claim ...".

Claim 5 is vague and indefinite in reciting, "an effective amount of adenosine in association with an antithrombotic" because it is unclear, as recited, what is encompassed in using the term "effective" which is a subjective term that lacks a

comparative basis for defining its metes and bounds. It is further unclear how adenosine is intended to be structurally or functionally associated with the antithrombotic.

Claim 6 is indefinite in reciting "LMW". Acronyms or abbreviations must be recited at least one time in a set of claims. See also claims 15 and 18.

Claim 10 is vague and indefinite in reciting, “an effective amount of adenosine” because it is unclear, as recited, what is encompassed in using the term “effective” which is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 11 is vague and indefinite in reciting, “an effective amount of adenosine” because it is unclear, as recited, what is encompassed in using the term “effective” which is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 12 is vague and indefinite in reciting, “an effective amount of adenosine” because it is unclear, as recited, what is encompassed in using the term “effective” which is a subjective term that lacks a comparative basis for defining its metes and bounds.

Claims 13-15 have improper antecedent basis problems in reciting, “A method according to claim …”.

Claim 18 has improper antecedent basis problem in reciting, “A method according to claim …”.

Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from previously recited claims in the alternative. See MPEP § 608.01(n).

In claim 20, "The method of any of claim 5", should be --The method of claim 5--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 10-15, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sollevi (US 5,731,296).

Sollevi discloses administering to human beings an effective amount of adenosine by continuous infusion for use in treating various disease conditions (Abstract). Sollevi specifically reports that adenosine has a variety of biological effects whether it is endogenously or exogenously administered, including inhibition of platelet aggregation (anti-aggregatory effect), antithrombic effect (inhibit clot formation), vasodilation, peripheral and cardiovascular effects, and hypotensive activity. Accordingly, adenosine is administered for use in preventing or treating thromboembolic disorders such as hypertension, arterial thrombosis, ischemia, and peripheral vascular diseases (see column 1, lines 23-36, column 2, lines 39-64, column 3, lines 11-15, and column 20, lines 12-28). Adenosine is administered to a patient in any pharmaceutically

acceptable carrier, i.e. diluent such as isotonic saline, or form (see column 3, lines 27-61). Sollevi also discloses administering adenosine in combination with another antithrombic such as heparin for the purpose of platelet protection during cardiopulmomary bypass (see Example VI).

5. Claim 2, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (FASEB Journal, 9 (3): page A322 (1995)).

Wang et al. teach that administration of adenosine inhibits thrombosis in dogs and partially protects against renewal of thrombus formation by epinephrine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sollevi (US 5,731,296) in view of Foster et al. (US 4,444,879).

Sollevi discloses administering to human beings an effective amount of adenosine by continuous infusion for use in treating various disease conditions (Abstract). Sollevi specifically reports that adenosine has a variety of biological effects whether it is endogenously or exogenously administered, including inhibition of platelet aggregation (anti-aggregatory effect), antithrombic effect (inhibit clot formation), vasodilation, peripheral and cardiovascular effects, and hypotensive activity. Accordingly, adenosine is administered for use in preventing or treating thromboembolic disorders such as hypertension, arterial thrombosis, ischemia, and peripheral vascular diseases (see column 1, lines 23-36, column 2, lines 39-64, column 3, lines 11-15, and column 20, lines 12-28). Adenosine is administered to a patient in any pharmaceutically acceptable carrier, i.e. diluent such as isotonic saline, or form (see column 3, lines 27-61). Sollevi also discloses administering adenosine in combination with another antithrombic such as heparin for the purpose of platelet protection during cardiopulmomary bypass (see Example VI).

Sollevi differs from the instant invention in failing to disclose adenosine, antithrombotics, and pharmaceutical carriers in a kit format.

Foster et al. discloses reagents, i.e. immunoglobulins and containers (vials) in a kit format for use in an assay (see column 15).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the adenosine, antithrombics, pharmaceutical carriers, and containers taught by Sollevi into a kit arrangement as taught by Foster et al. because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

7. No claims are allowed.

Remarks

8. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988, Abstract) identify and determine a biologically active ingredient from safflower Carthamus tinctorius L. The biologically active ingredient is a platelet aggregation inhibitor affecting platelet membrane receptor glycoprotein IIb/IIIa. This inhibitor is isolated by high performance liquid chromatography (HLPC).

Sollevi (US 5,534,504) discloses administering adenosine as an agent to treat thromboembolic disorders such as myocardial infarction in patients.

Kitakaze et al. (Circulation Research 69 (5): 1402-1408 (November 1991)) teach that adenosine inhibits platelet aggregation in ischemic and myocardial patients.

Yamada (US 5,773,603) discloses novel O-alkylated adenosine or adenosine derivatives which have excellent adenosine deaminase inhibiting action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R Gabel whose telephone number is (703) 305-9297. The examiner can normally be reached on Monday-Thursday 6:00 AM to 3:30 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
January 6, 2003

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641